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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DICICCO, JOHN R

ART UNIT

PAPER NUMBER

4123

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,409	Applicant(s) ALCIDI, LUCIANO	
	Examiner JOHN R. DI CICCO	Art Unit 4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-14 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 10 is objected to because of the following informalities: The third line of claim 10 should not include the words "and the" after "to vary the" and before "output power." The third line should read "and able to vary the output power in order to keep skin temperature at a." Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 6-8, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiksell et al. (4,846,196). Furthermore, 35 U.S.C. 112, sixth paragraph has been invoked due to "means plus function" language in claims 1 and 14.

With respect to claim 1, Wiksell et al. disclose an apparatus for non-destructive hyperthermia therapies (abstract), the apparatus comprising: generating means for generating radio-frequency electromagnetic radiation, connectable to application means for the application of said radiation to a skin portion of a human body (abstract), said application means comprising an active electrode and a reference electrode (Fig.1, #2, #6), said active electrode being provided with a sensor means for the detection of skin temperature of the skin portion (column 9, lines 50-51), said sensor means including at

least a sensor incorporated in said active electrode (column 7, lines 26-28 and column 9, lines 50-51).

With respect to claim 6, Wiksell et al. disclose said electrodes, which consist of conductive plates or membranes (column 6, lines 31-37).

With respect to claim 7, Wiksell et al. disclose structure of the active electrode is complementary shaped with respect to the skin portion of the human body region of the patient to be treated (column 6, lines 31-37).

With respect to claim 8, Wiksell et al. disclose said reference electrode, which has dimensions larger than those of the active electrode (column 4, lines 8-17).

With respect to claim 14, Wiksell et al. disclose an apparatus for non-destructive hyperthermia therapies (abstract), the apparatus comprising: generating means for generating radio-frequency electromagnetic radiation; and application means connected to said generating means for the application of said radiation to a skin portion of a human body (abstract), said application means comprising an active electrode and a reference electrode (Fig. 1, #2, #6), said active electrode being provided with a skin temperature sensor means for the detection of skin temperature of the skin portion (column 9, lines 50-51), said sensor means including at least a sensor part directly incorporated in or directly connected to said active electrode (column 7, lines 26-28 and column 9, lines 50-51).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 4 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiksell et al. (4,846,196) in view of Cosman et al. (2002/0111617). Furthermore, 35 U.S.C. 112, sixth paragraph has been invoked due to “means plus function” language.

With respect to claim 4, Wiksell et al. disclose the invention set forth above but fail to disclose said means for the detection of the skin's temperature which comprises a sensor which can be connected to the apparatus and removably associated with the active electrode, said active electrode having a seat complementarily matching a corresponding connector of the sensor as in the instant claimed invention.

However, Cosman et al. teach two electrode rings on a flexible catheter with removable insulative bands and temperature sensors (column 4, lines 27-32; Fig. 8).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with removable temperature sensors as taught by Cosman et al. because it would have enabled the device to incorporate removal or attachment of temperature sensors.

With respect to claim 11, Wiksell et al. disclose the invention set forth above but fail to disclose the apparatus wherein further comprising measuring means for measuring the output power and the impedance in correspondence of the application means as in the instant claimed invention.

However, Cosman et al. teach a generator which can have many control and readout functions associated with the RF parameters of the ablation process which

include display output power, current, voltage, impedance, or other parameters associated with the heating process (columns 6-7, lines 65-2).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with a generator which has many control and readout functions as taught by Cosman et al. because it would have enabled the device to display output power and impedance, thus enabling manual control of the parameters.

With respect to claim 12, Wiksell et al. disclose the invention set forth above but fail to disclose the apparatus wherein further comprises means to preset the duration of the treatment as in the instant claimed invention.

However, Cosman et al. teach control aspects of the generator that manually, automatically, or by computer control govern and monitor the process and parameter display of RF signal application to the electrodes and time parameters during the procedure (column 7, lines 3-7). Furthermore, Cosman et al. teach the electrode which is used to heat tissue for three minutes and five minutes (column 6, lines 60-64).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with a generator as taught by Cosman et al. because it would have enabled the device to control time parameters of the treatment.

8. Claims 5, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiksell et al. (4,846,196) in view of Takayama et al. (5,003,991). Furthermore, 35 U.S.C. 112, sixth paragraph has been invoked due to "means plus function" language.

With respect to claim 5, Wiksell et al. disclose the invention set forth above but fail to disclose the said sensor means for the detection of the skin's temperature which are connected to a control circuit connectable to and acting on said generating means for generating radio-frequency radiation as in the instant claimed invention.

However, Takayama et al. teach a controller which supplies a control signal to the variable impedance matching circuit such that the input impedance of the load circuit including two electrodes selected by the switch is matched to the output impedance of the RF power supply device including the co-axial cable (column 7, lines 51-56) and for instance, when the electrodes are switched into or out of the circuit by the switch, the RF power is decreased to zero, and when the sensed temperatures increase, the RF power is switched OFF or ON (column 7, lines 61-66).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with a control circuit as taught by Takayama et al. because it would have enabled the device to switch the RF power on or off depending on the sensed temperature from the control circuit.

With respect to claim 9, Wiksell et al. disclose the invention set forth above but fail to disclose the apparatus further comprising additional active electrodes connected to a switch device able to connect in sequence said active electrodes to said generating means for generating radio-frequency radiation as in the instant claimed invention.

However, Takayama et al. teach a selection switch which serves to connect a first combination of the first and second electrodes and or a second combination of the second and third electrodes and to a high frequency power supply source so that an

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electric field of a Radio Frequency can be applied across the electrodes (column 5, lines 31-37; Fig. 3).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with a switch as taught by Takayama et al. because it would have enabled the device to connect electrodes with a power supply source so that an electric field of a Radio Frequency can be applied across the electrodes (Fig. 3).

With respect to claim 10, Wiksell et al. disclose the invention set forth above but fail to disclose the apparatus further comprising means for adjusting the temperature reached on the skin and able to vary the output power in order to keep skin temperature at a preset value as in the instant claimed invention.

However, Takayama et al. teach a hyperthermia apparatus for effecting the thermotherapy by heating a cancer locally including two outside-body electrodes, and a switch connected between the high frequency power supply circuit and the electrodes for selectively supplying the high frequency power to two electrodes so that the cancer can be locally heated to a desired high temperature (abstract).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with a switch as taught by Takayama et al. because it would have enabled the device to selectively supply power to the outside-body electrodes at a desired temperature.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wiksell et al. (4,846,196) in view of Turner (4,798,215). Furthermore, 35 U.S.C. 112, sixth paragraph has been invoked due to “means plus function” language.

Wiksell et al. disclose the invention set forth above but fail to disclose the apparatus further comprising means for connection with an electronic processor as in the instant claimed invention.

However, Turner teaches the hyperthermia and receiver subsystems which include, respectively, a power source and radiometer connected to a switch controlled by a central processing unit (abstract).

It would have been obvious to one of ordinary skill in the hyperthermia art to have modified Wiksell et al. with a processor as taught by Turner because it would have enabled the device a processor to be connected with, which inherently requires a means for connection.

Response to Arguments

10. Applicant's arguments filed 12/26/07 have been fully considered but they are not persuasive.

11. The Examiner has withdrawn the drawings and specifications objections. In addition, the initial claim objections were withdrawn; however, a new claim objection was found and is noted above. Furthermore, the 112 claim rejection has been withdrawn.

The applicant argues that Wiksell et al. fail to anticipate and fail to suggest: “active electrode being provided with a sensor means for the detection of skin temperature of the skin portion, said sensor means including at least a sensor incorporated in said active electrode.”

The Examiner disagrees. The temperature sensor is located in the treatment electrode (column 9, lines 50-51), and temperature readings are taken from the surrounding tissue (column 9, lines 58-59 and column 5, lines 29-38).

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN R. DI CICCIO whose telephone number is (571)270-5039. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRD

/Joseph S. Del Sole/
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